K100270

510(k) Summary

This 510(k) summary is being submitted in accordance with 21 CFR 807.92

MAR 29 2010

1. SUBMITTER'S INFORMATION

NAME: Palomar Medical Technologies, Inc.

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Phone: (781) 993-2300
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CONTACT: Sharon Timberlake, MSHS, RAC, CCRA
Director of Regulatory Affairs

DATE PREPARED: January 25, 2010

2. DEVICE INFORMATION

TRADE/PROPRIETARY NAME: Artisan™ Aesthetic System

COMMON/USUAL NAME: Light and Laser System

CLASSIFICATION NAME: Laser surgical instrument for use in general and plastic surgery and in dermatology
(21 CFR § 878.4810)

PRODUCT CODES: GEX, ONG

3. PREDICATE DEVICES

Palomar Medical Technologies, Inc.
Lux2940 Handpiece
K083900, K071768

Palomar Medical Technologies, Inc.
Lux1540 Handpiece
K090195, K091446

Palomar Medical Technologies, Inc.
Lux1440 Handpiece
K073583, K091446

Palomar Medical Technologies, Inc.
Palomar StarLux Pulsed Light System
K041086, K033549

K100270

4. INTENDED USE

The Lux1540 Handpiece is intended for use in coagulation of soft tissue, skin resurfacing procedures as well as treatment of melasma, striae, acne scars and surgical scars.

The Lux1440 Handpiece is intended for use in dermatological procedures requiring coagulation of soft tissue and skin resurfacing procedures.

The Lux2940 Handpiece is intended for use in surgical applications requiring the excision, incision, ablation, vaporization, and coagulation of soft tissue. Soft tissue includes skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, calculi or fragments, mucous membrane, lymph vessels and nodes, organs, and glands in the following indications: skin resurfacing, treatment of wrinkles, epidermal nevi, telangiectasia, spider veins, actinic chelitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision (including acne scars), debulking benign tumors, debulking cysts and superficial skin lesions. The Lux2940 Fractional Handpiece is intended for use in dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, pigmented lesions, and vascular dyschromia.

The MaxG Handpiece is intended for treatment of benign pigmented epidermal and cutaneous lesions, including but not limited to lentigines, nevi, melasma, café-au-lait warts, scars, striae, and the treatment of vascular lesions including but not limited to port wine stains, hemangiomas, angiomas, telangiectasias, rosecea, facial and leg veins.

5. DEVICE DESCRIPTION

The Artisan Aesthetic System consists of a console with an internal power supply, chiller, and electronics. The light and laser handpieces connect to the system via the console connection port.

6. PERFORMANCE DATA

The review of the technical characteristics, indications for use, risk analysis, verification and validation information provided in the 510(k) Premarket Notification demonstrates that the Artisan Aesthetic System is substantially equivalent to its predicate device.

7. SUBSTANTIAL EQUIVALENCE

The Artisan Aesthetic System is substantially equivalent to its predicate devices when used according to its intended use. This is based on the information provided in this 510(k) Premarket Notification which demonstrates that the Artisan Aesthetic System shares the same technological characteristics, mechanism of action, intended use and physical properties when compared to its predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Palomar Medical Technologies, Inc.
% Ms. Sharon Timberlake, MSHS, RAC, CCRA
15 Network Drive
Burlington, Massachusetts 01803

MAR 29 2010

Re: K100270
Trade/Device Name: Artisan™ Aesthetic System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and Plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX, ONG, ONF
Dated: January 28, 2010
Received: January 29, 2010

Dear Ms. Timberlake:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100270

Device Name: Artisan™ Aesthetic System

Indications for Use:

The Lux2940 Fractional Handpiece optics is intended for use in dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, pigmented lesions, and vascular dyschromia.

The Lux2940 Handpiece is intended for use in surgical applications requiring the excision, incision, ablation, vaporization, and coagulation of soft tissue. Soft tissue includes skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, calculi or fragments, mucous membrane, lymph vessels and nodes, organs, and glands in the following indications: skin resurfacing, treatment of wrinkles, epidermal nevi, telangiectasia, spider veins, actinic chelitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision (including acne scars), debulking benign tumors, debulking cysts and superficial skin lesions.

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Neil R P Ogden for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100270

The MaxG Handpiece is intended for treatment of benign pigmented epidermal and cutaneous lesions, including but not limited to lentigines, nevi, melasma, café-au-lait warts, scars, striae, and the treatment of vascular lesions including but not limited to port wine stains, hemangiomas, angiomas, telangiectasias, rosecea, facial and leg veins.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark P Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100270